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Santiago de Chile, February 11, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
U.S.A.

RE: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Docket No. 02N-0276

The Chilean Exporters Association (ASOEX) is a private non-profit trade association that represents Chilean fresh fruit and vegetable export companies. Members of ASOEX accounts for nearly 85% of total Chilean produce exports.

The fruit and vegetables industry is one of Chile's most important economic activities, with annual returns exceeding USD1.6 billion (FOB Chilean ports). It accounts for 65% of employment in agriculture and 9% of the country's total labour force.

ASOEX hereby, submits these additional comments on the Interim Final Rules of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002".

ASOEX has received an advisory from the United Fresh Fruit and Vegetable Association (UFFVA) indicating that certain farms may be "facilities" within the meaning of the food facility registration requirement of the Bioterrorism Act. The advisory states that -as a result of work meetings with FDA representatives- it was concluded that "farms" on which fruit and vegetables are packaged that go directly to the final consumer in the USA (as for instance, clam-shells, plastic sleeves, cello bags) are not included in the definition of "farm" as provided in the Interim Final Rule. Consequently, those farms have to register with the FDA.

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The language of §1.227(8) defining “packaging” may be broad enough to include consumer packages such as clam shells and cell sleeves. Packaging solely for consumer use is excluded from the definition of “packing” under §1.227(b)(9). However, if a farm boxes or wraps its produce for the sole purpose of transportation, it is not required to register, because such activity is considered “packing” under §1.227(b)(9). The packaging in Chile serves a dual use; it is necessary to protect the product during shipping, but it is also a consumer-ready package for the sole and necessary purpose of minimizing excess handling and consequent damage to the fruit. Such dual use of packaging should not trigger a registration of the farm.

Furthermore, FDA’s new interpretation of the Interim Final Rule significantly departs from the guidance given by FDA officials at the Embassy Training Seminar that took place in Washington DC, on November 6th and 7th, 2003. The seminar was attended by the Chilean Agricultural Attaché and representatives of the Chilean private sector. During the seminar, the FDA indicated that the activities described above (i.e., packaging produce directly at the farm where the produce is grown) are considered “farm activities” and hence such an establishment is exempted from registration as a food facility with the FDA.

The new interpretation would directly affect trade of two major Chilean fruit species exported to the US market: table grapes and berries. The latter is particularly important since this industry is made up of a large number of small growers whose farms are located throughout Chile’s territory. Additionally, many growers deliver their products to more than one export company, a fact that makes the situation even more complicated. To a lesser extent, these grower-exporter relationships also hold true for table grapes.

Berry growers have been trained and are currently receiving advice from qualified professionals of their export companies in order to enable them to comply with both phytosanitary requirements and other regulations established by the US agencies for their respective products to gain entry into the United States.

Due to the highly perishable nature of raspberries, blueberries and strawberries –all of which tolerate only minimum handling without damage– berries are packaged directly at the farm where they are produced, in the same containers (clam-shells) that reach the final consumer. After packaging at the farm of origin, these products are taken to holding facilities where they are kept in cold chambers until shipment. At these holding facilities a thorough quality control is carried out in order to ensure that the product will reach its market of destination in perfect conditions. Afterwards, the containers (clam-shells and boxes) are labelled and palletized.



These holding facilities keep reliable records of all products they receive, including the identification of the grower, date of packaging, place of packaging, etc. Consequently, there is absolutely no problem in identifying at this level, the exact origin of a given product, should the need arise. All of these holding facilities have already been duly registered with the FDA and appear on the Prior Notice of Imported Food for product that moves through them.

For the foregoing reasons, ASOEX respectfully requests the FDA to clarify the definition of "farm" so that the activities pertaining to berry and table grape farms be included in the definition of "Farm" and consequently will continue to be exempted from registration.

If berry farms are not exempted from registration most growers will have to modify their present packaging processes and be forced to send directly their products to holding facilities for packaging. This will inevitably affect the quality of the product reaching US consumers. Alternatively, the time period for registration of farms that use dual purpose packaging should be extended, specially in view of FDA's inconsistent guidance on this issue.

ASOEX would like to emphasize that, in our opinion, the proposed clarification would achieve the security levels that are intended by the FDA regulations and a higher degree of flexibility and quality in the marketing of perishable products.

Sincerely yours,

CHILEAN EXPORTERS ASSOCIATION

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